Louisiana Office of Public Health Laboratories	
Test Name	Neonatal IRT Time-Resolved Fluoroimmunoassay
PHL Location	Central Laboratory 1209 Leesville Avenue Baton Rouge, Louisiana 70802
CPT Code	83516
Synonyms	IRT
Brief Description of Test	Quantitative determination of human Immunoreactive Trypsinogen in blood specimens dried on filter paper as an aid in screening newborns of Cystic Fibrosis.
Possible Results	Elevated ; Normal
Reference Range	≥ 60ng/mL=Elevated; <60ng/mL=Normal
Specimen Type	Neonatal Dried Blood Spot
Specimen Container(s):	Shipping Envelopes
Minimum volume accepted:	Minimum of 2 completely filled blood spot circles
Collection Instructions	Blood Specimens should be taken directly from a heel prick onto filter paper and, allowed to dry for at least 3 hours in a horizontal position.
Storage and Transport Instructions	Storage of samples in an environment with elevated temperatures and humidity increases the risk of false positive screening results. Transport or mail the specimen to the laboratory with 24 hours of collection.
Causes for Rejection	Specimen > 14 days old, clotted or layered, serum rings, scratched or abraided, insufficient quantity for testing, not completely dry before mailing, blood applied to both sides of the filter paper, diluted discolored or contaminated, collection using capillary tubes containing EDTA, >12 months old, circles not completely filled.
Limitations of the Procedure	Samples spot not uniformly saturated with blood - sample spots punched too close to the edge of the blood spot - poorly collected and improperly dried specimens - non-eluting blood spot due to deterioration of sample caused by exposure to heat and humidity - contamination of blood spot filter paper with fecal material Heterophilic antibodies in the sample may interfere with the assay (16,17). Hematocrit values in the blood sample may affect the measured hTSH concentration
Interfering Substances	Icteric (unconjugated bilirubin ≤171 µmol/L, equivalent to 10mg/dL in blood and conjugated bilirubin ≤197 µMmol/L, equivalent to 16.6 mg/dL in blood), lipemin (intralipid ≤15 mg/dL in blood) and hemolytic (additional hemoglobin ≤1g/dL in blood) specimens do no interfere with the assay. Specimens containing EDTA up to 9.8mg/mL blood. Na-citrate up to 0.0645 mol/L blood or Li-heparin up to 0.375 mg/ml blood do not interfere with the assay.
References	GSP Neonatal IRT kit package insert
Additional Information	N/A
Release Date	11/2013

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